



Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

December 19, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 17

Jon C. Ratliff
President and Owner
Wayzata Bay Products, Inc.
4358 South County Road 92
St. Bonifacius, Minnesota 55375

Dear Mr. Ratliff:

During our inspection of your Wayzata Bay Products, Inc., an over-the-counter (OTC) drug manufacturing operation located in St. Bonifacius, MN, on October 15, 16, 23, and 31, 2001, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your OTC drug product is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include, but are not limited to, the following:

1. Failure to assure that each person engaged in the manufacturing, processing, packing, or holding of a drug product shall have the education, training, experience to enable that person to perform the assigned functions [21 CFR 211.25(a)] in that there is no documentation of current cGMP training for your employee.
2. Failure to have a written testing program designed to assess the stability characteristics of drug products (21 CFR 211.166).
3. Failure to have an expiration date on your OTC product or, in lieu of expiration dating, failure to have appropriate stability data for at least three years to support the lack of an expiration date on your OTC drug product [21 CFR 211.137(a) and (h)].
4. Failure to have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including

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identification and strength for each active ingredient [21 CFR 211.165(a)] in that there is no finished product testing for your OTC drug product.

5. Failure to have written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall be followed in the execution of the various production and process control functions [21 CFR 211.100 (a) and (b)] in that no formal protocol has been prepared for the validation of the water system, nor has your water system been validated.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

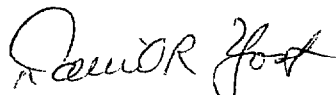
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

In addition, removing "sanitizing" from the labeling does not alter the categorization of your waterless hand sanitizing gel as a drug. Its labeling does not make it a drug; the ingredients make this product a drug.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,



David R. Yost
Acting Director
Minneapolis District

CAH/ccl